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K001283
p1/2

14. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Device Name

LifeMate™ Hemofiltration System

Submitter Name , Address, and Contact Information

NxSTAGE Medical, Inc.
3 Highwood Drive
Tewksbury, MA 01876

Contact Person:	Jeffrey Burbank, President
Phone:	978-863-4555
Fax:	978-863-4524

Common, Classification & Proprietary Names

Common Name:	hemofiltration system
Classification Name:	high permeability hemodialysis system
Proprietary Name:	LifeMate Hemofiltration System

Device Classification

Classification:	Class II*
CFR Reference:	21 CFR 876.5860
Classification Panel:	Gastroenterology and Urology Devices
Product Code:	KDI

**Reclassification to Class II effective May 1, 2000.*

Indications for Use

The LifeMate Hemofiltration System is indicated for treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration. All treatments must be administered by a health care provider, under physician prescription.

Device Description

The LifeMate Hemofiltration System consists of the LifeMate cycler unit and the LifeMate Cartridge.

The LifeMate cycler unit performs the following functions:

- Loads and primes the LifeMate Cartridge and flushes the filter
- Performs pressure tests and alarms tests
- Pumps blood from the patient, through the filter, and back to the patient

- Balances sterile replacement fluid infused with waste fluid removed
- Monitors the treatment and alerts the operator when treatment interventions are needed
- Rinses back blood to the patient at the conclusion of treatment.

The LifeMate system may be used only with the LifeMate Cartridge. The LifeMate Cartridge is a sterile pathway, single use extracorporeal blood circuit and fluid management device. The Cartridge provides the blood and fluid interface to the Cycler pumps, clamps and sensors.

Non-Clinical Testing

Verification and validation testing of the LifeMate System demonstrates that the device meets specifications and applicable international standards pertaining to medical electrical equipment safety, electromagnetic compatibility, biocompatibility and sterility assurance.

Predicate Devices

The LifeMate Hemofiltration Cycler is substantially equivalent to:

Device Name	*Manufacturer*	*510(k)*
BSM22 / VPM	Hospal	K852134, K902588
CentrySystem 3 (C3)	COBE	K851306, K970253
Diapact CRRT	B. Braun	K963440
Prisma CFM	Gambro	K946279, K981681

The LifeMate Cartridge Blood Tubing Set is substantially equivalent to:

Device Name	*Manufacturer*	*510(k)*
CentrySystem 3 Cartridge Blood Tubing Set	Cobe	K851306
Prisma™ Set	Gambro	K946279
ReadySet® Blood Tubing Set	Medisystems	K811839, K953823

Substantial Equivalence

The LifeMate Hemofiltration Cycler and LifeMate Cartridge were shown to be substantially equivalent in intended use, design, technological characteristics, materials and system features and functions to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2001

Jeffrey H. Burbank
President and CEO
NxStage Medical, Inc.
3 Highwood Drive
TEWKSBURY MA 01876

Re: K001283
LifeMate™ Hemofiltration System
Dated: October 18, 2000
Received: October 19, 2000
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Burbank:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

5. Statement of Indications for Use (FDA Form)

510(k): K001283

Device: **LifeMate™ Hemofiltration System**

Indications for Use:

The LifeMate Hemofiltration System is indicated for treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration. All treatments must be administered by a health care provider, under physician prescription.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001283